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TO:	Mail Stop AF ATTN: Examiner Fenn C. Mathew Art Unit: 3764	FROM:	DAVID J. KENEALY Cermak & Kenealy LLP
FAX:	571-273-8300	REF. NO:	MA3005-0031
VOICE:		PAGES	11 (incl. this sheet)
App. No.:	09/870,672	DATE:	January 3, 2006

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- 1) This facsimile Certification cover sheet (1 pg)
- 2) Notice of Appeal (1 pg)
- 3) Petition for Extension of Time (2 pp)
- 4) Pre-Appeal Brief Request for Review Cover Sheet (1 pg)
- 5) Pre-Appeal Brief Request for Review (5 pp)
- 6) PTO-2038 (1 pg)

David J. Kenealy
Registration Number 40,411

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PRE-APPEAL BRIEF REQUEST FOR REV	EW	N/ A 300	MA3005-0031		
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United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]	09/870,672		June 1, 2001		
on	First Named Inventor				
Signature	Ryota SUGIMOTO				
	Art Unit	ĮE	xaminer		
Typed or printed name	8651		Mathew, F. C.		
Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.					
This request is being filed with a notice of appeal.					
The review is requested for the reason(s) stated on the attached sheet(s).  Note: No more than five (5) pages may be provided.					
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applicant/inventor.	$\smile$	5	Signatura		
assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)	Da	vid J. Ke	nealy or printed name		
attorney or agent of record.  Registration number 40,411	<u>70</u>	3-778-661			
_		Telep	hone number		
attorney or agent acting under 37 CFR 1.34.		January	3, 2005		
Registration number if acting under 37 CFR 1.34			Date		
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.					

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JAN 0 3 2005

Patent Attorney's Docket No. MA3005-0031

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of	)		
Ryota SUGIMOTO	) Group Art Unit: 3764		
Application No.: 09/870,672	) Examiner: Mathew, Fenn C.		
Filed: June 1, 2001	) Confirmation No.: 8651		
For: IMPLANTABLE TUBULAR DEVICE	)		

## PRE-APPEAL BRIEF REQUEST FOR REVIEW

Commissioner for Patents Alexandria, Virginia 22313

Sir:

In response to the Final Official Action dated September 7, 2005, the response period extending through January 7, 2006 by a one-month petition for extension of time and Notice of Appeal filed herewith, Applicant requests a Pre-Appeal Brief Review in accordance with the guidelines set forth in the July 12, 2005 Official Gazette Notice. Reconsideration of this application by a three Examiner panel is requested in view of the following remarks which identify the errors in facts, and the omission of essential elements required to establish a prima facie rejection.

## Summary of Final Office Action and Status of Case

In the September 7, 2005 Office Action, claims 1, 4, 5, 9-13, 20, 22, 23, 32-37, and 38-43 were rejected under 35 U.S.C. §103(a) over U.S. Patent No. 6,293,967 to Shanley (Shanley'967) in view of Palmaz et al. WO 99/23977 (Palmaz'977). Shanley'967 is used for an alleged teaching of a basic extendable stent structure. Palmaz'977 is used as an alleged teaching of grooves on an interior surface of a stent structure.

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Dependent claims 14-19, 44 and 45 were rejected under 35 U.S.C. §103(a) over Shanley'967 in view of Palmaz'977 and further in view of U.S. Patent No. 5,788,979 to Alt et al. (Alt'979). No claims were indicated as allowable.

Various forms of rejections have been set forth in previous Office Actions. It should be noted that this application was initially subjected to three non-final Office Actions, followed by a final Office Action, a fourth non-final Office Action, and now the present final Office Action. Applicant's representatives also conducted three separate personal interviews with the Examiner during prosecution.

The claims currently pending in this application are claims 1, 4, 5, 9-20, 22, 23, and 32-45. Claims 1, 32, and 33 are the only independent claims.

### **Summary of Claimed Invention**

The claimed invention is directed to an implantable tubular device (e.g., a stent or other tubular device) that has deformable portions formed as grooves on either an inner or outer surface of the tubular device. The grooves form a predetermined angle with respect to an axial direction of the implantable tubular device, and when one of the grooves is prolonged it forms either "an endless annular configuration" (claims 1 and 32) or "a spiral configuration" (claim 33). The grooves are located/formed on the bent portions of the annular members of tubular device.

The grooves serve to allow the implantable tubular device to deform with greater ease, for example, at the bent portions of the annular members.

#### **Factual Errors Requiring Review**

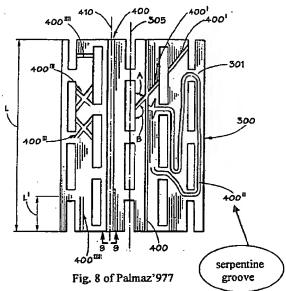
In the September 7, 2005 Final Office Action at paragraph 4, the Examiner provides the following argument in support of the present rejections:

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[T]he teachings of Palmaz('977) specifically cite the use of grooves on any portion of a stent. With regards to the annular configuration, Palmaz('977) specifically states that it may be desirable to have symmetrical relationship between the grooves, or that one may form a serpentine pattern. One of ordinary skill in the art would have been inclined to provide grooves on any and all portions of a stent based on the teachings of Palmaz.

It is respectfully submitted that the Examiner has mistakenly relied on the term "serpentine" as it appears in the Palmaz'977 specification for the alleged teaching of the

"endless annular" or "spiral" features of Applicant's independent claims. Instead of describing an endless annular or spiral configuration, the term "serpentine" is used to describe the single groove 400", which is shown in Fig. 8 of Palmaz'977 (reproduced at right with serpentine groove 400" highlighted) to be a single groove 400" formed as a snake-like and randomly meandering groove located in the inner surface of the stent 300. This groove 400" cannot be



considered to be "an endless annular configuration" or "spiral configuration" as recited in Applicant's claims.

With regard to the other types of grooves disclosed in the Palmaz'977 specification, grooves 400" are described as "grooves...provided in a cross-hatched manner." Groove 400" is described as a groove located at an angle with respect to the longitudinal axis of the stent 300.

It is believed that the Examiner may be attempting to read into the Palmaz'977 specification a teaching that the grooves 400' or 400'" can be continuously extended to form endless annular or spiral configurations. This teaching is simply not provided by the

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Palmaz'977 reference. Furthermore, even if (assuming arguendo) such a teaching were provided, the claimed invention would still not be met or made obvious by such a disclosure. Claims 1 and 33 include the feature of the grooves "formed on the bent portions of the wavy annular members," while claim 32 includes the feature of the grooves "located on each of the plurality of bent portions." These claimed location/placement features are neither taught nor disclosed either alone or in combination in either Palmaz'977 or Shanley'967. There would have been no reason to form the grooves of Palmaz'977 in the locations recited in Applicant's claims because Palmaz'977 was solely interested in providing grooves "so as to increase the rate of migration of endothelial cells on, and over, the inner surface of the intravascular stent." (See lines 18-20 of the Palmaz'977 specification). By contrast, the location of the grooves as claimed in the present application allows the tubular device to deform with greater ease, for example, at the bent portions of the annular members.

#### Prime Facie Case for Obviousness Not Met

At least two claimed features are not disclosed or taught in either of the applied references (either alone or in combination with each other). Specifically, with regard to claims 1 and 33, neither Palmaz'977 nor Shanley'967 disclose or teach at least the features of: 1) an implantable tubular device that has a deformable portion formed as a groove and configured such that when it is prolonged it forms an endless annular configuration; or 2) a deformable portion formed as a groove and formed on the bent portions of the wavy annular members. With regard to claim 32, neither Palmaz'977 nor Shanley'967 either alone or in combination disclose or teach at least the features of: 1) a deformable portion formed as a groove and configured such that when prolonged it forms a spiral configuration; or 2) a plurality of deformable portions located on each of the bent portions.

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CERMAK & KENEALY LLP

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In order to establish a prime facie case of obviousness, according to M.P.E.P. § 2142,

"the prior art reference, or references when combined, must teach or suggest all the claim

limitations." (emphasis added). As pointed out above, the present rejection fails to meet at

least this first prong of the test for establishing a prime facie case of obviousness. Applicant

further relies on the arguments set forth at the last paragraph of page 10 and extending

through the first full paragraph on page 12 of Applicant's Response filed on June 25, 2005 to

provide a more thorough analysis of each of the three prongs necessary to show a prime facie

case for obviousness, and to demonstrate the deficiencies of the rejections set forth in the

September 7, 2005 final Office Action.

Conclusion

In the interest of brevity, Applicant does not provide all arguments that would support

an appeal for each of the pending and rejected claims. However, it is respectfully submitted

that this case is in immediate and clear form for allowance based on the clear errors and

omissions cited above. Accordingly, an early indication via a Notice of Allowability that all

claims are allowable is respectfully requested. Should any questions arise in connection with

this application or should the Examiner believe that a telephone conference with the

undersigned would be helpful in resolving any remaining issues pertaining to this application,

the undersigned respectfully requests that he be contacted at the number indicated below.

Respectfully submitted,

CERMAK & KENEALY LLP

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Date: January 3, 2006

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